UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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JOHN TRISVAN,

Plaintiff

Civil Action No.: 16 CF 0084 (MKB)(LB)

-against-

TOM HEYMAN, *President, Johnson and Johnson Development Corporation*; ALEX GORSKY, *Chairman and CEO, Johnson and Johnson*; JOAQUIN DUARTO, *Chairman*; JOHNSON AND JOHNSON DEVELOPMENT CORPORATION; JANSSEN PHARMACEUTICALS; SIR PHILLIP HAMPTON, *Chairman, Glaxosmithkline*; ANDREW WITTY, *CEO, Glaxosmithkline*; GLAXOSMITHKLINE, LLC.

Defendants.

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MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS SIR ANDREW WITTY, SIR PHILIP HAMPTON, AND GLAXOSMITHKLINE LLC'S MOTION TO DISMISS PLAINTIFF'S AMENDED COMPLAINT

Pursuant to Federal Rules of Civil Procedure 12(b)(2), (5), and (6), Defendants Sir Andrew Witty, Sir Philip Hampton, and GlaxoSmithKline LLC (collectively, "GSK Defendants") move to dismiss Plaintiff's Amended Complaint because (1) this Court lacks personal jurisdiction over Plaintiff's claims against Sirs Witty and Hampton, (2) Plaintiff has failed to properly effect service of process upon Sirs Witty and Hampton, and (3) Plaintiff's Amended Complaint does not satisfy federal pleading requirements, as it is untimely and it does not meet *Twombly* / *Iqbal* pleading standards.[1] In support, GSK Defendants state:

[1] At the time this motion was served on Plaintiff, and to GSK LLC's knowledge, Plaintiff had not served GSK LLC with his Amended Complaint. By joining this Motion to Dismiss, GSK LLC does not waive service of the summons and complaint nor does it waive any challenge to the Court's personal jurisdiction over GSK LLC.

I. PRELIMINARY STATEMENT

The allegations in Plaintiff's Amended Complaint are essentially identical to those made in his Original Complaint, which was dismissed by the Court on March 24, 2017. Doc. No. 33. Plaintiff contends that he began taking Wellbutrin® and Risperdal® ("the medications")[2] over fifteen years ago and as a result, he has suffered an array of maladies, including weight gain, hypertension, gynecomastia, and fatty liver disease. In an effort to recover "no less than 15 million U.S. dollars" for his claimed injuries, Plaintiff has sued GlaxoSmithKline LLC ("GSK LLC") as well as the former CEO (Sir Andrew Witty) and the current Non-Executive Chairman (Sir Philip Hampton) of GSK LLC's indirect parent company, GlaxoSmithKline plc ("GSK plc").[3]

GSK Defendants appreciate that courts must afford *pro se* plaintiffs a good degree of procedural latitude. However, Plaintiff's action, even in its amended form, is a vague and puzzling jumble of unfounded accusations that still fails to show how this Court has jurisdiction over Hampton and Witty. The Amended Complaint also neglects to provide any allegations establishing the material elements of any recognizable claim against GSK LLC. Topping off these pleading failings is the fact that Plaintiff has brought his personal injury claims over a decade too late. The indecipherable Amended Complaint is the latest in a long list of frivolous suits filed by Plaintiff.[4] To prevent further abuse of the court system, GSK Defendants ask that Plaintiff's claims be dismissed with prejudice.

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[2] Wellbutrin® is an antidepressant manufactured by GlaxoSmithKline LLC. Risperdal® is an atypical antipsychotic agent indicated for the treatment of schizophrenia and manic episodes associated with Bipolar Disorder that is allegedly manufactured by Johnson and Johnson and/or Janssen Pharmaceuticals.

[3] In addition to GSK Defendants, Plaintiff names Tom Heyman, Alex Gorsky, Joaquin Duato, "Johnson & Johnson Development Corporation," and Janssen Pharmaceuticals.

[4] *See, e.g.*, *Trisvan v. Kalex Partners, LLC*, 1:16-cv-07000-MKB-ST, Doc. No. 4 (Jan. 26, 2017) (dismissing complaint seeking "no less than 10 million dollars" for alleged food poisoning injuries) (amended complaint pending); *Trisvan v. McKay*, No. 1:15-cv-8391, Doc. No. 5 (E.D.N.Y. Jan. 12, 2016)

II. BACKGROUND

On March 25, 2016, Defendants Witty and Hampton filed a joint Motion to Dismiss Plaintiff's Original Complaint. Aff. of Stephanie S. McGraw at ¶10.[5] On March 24, 2017, the Court entered a Memorandum & Order dismissing Plaintiff's claims against Witty and Hampton. Doc. No. 33 (the "Order"). Based upon Plaintiff's failure to set forth any allegations that Witty or Hampton had any contacts or business dealings in New York, and the fact that neither were employees, officers, or directors of the manufacturer of Wellbutrin® (GSK LLC), the Court held that it lacked jurisdiction over Witty and Hampton. *Id.* at 7.

The Court granted Plaintiff 30 days leave to file an amended complaint, which he did on April 14, 2017. Doc. No. 34. In addition to again naming Witty and Hampton, Plaintiff's Amended Complaint added GSK LLC as a defendant. On May 26, 2017, pursuant to the Court's briefing schedule, Defendants Witty, Hampton and GSK LLC served copies of the Notice of Motion to Dismiss Plaintiff's Amended Complaint, Aff. of Attorney Stephanie McGraw, and Memorandum of Law in Support of GSK Defendants' Motion to Dismiss Plaintiff's Amended Complaint via certified mail on Plaintiff.

III. LEGAL STANDARD

To survive dismissal under Rule (12)(b)(6), Rule 8 requires "more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)

(dismissing action brought against Bank of America executives seeking $1 million dollars because bank denied him a mortgage); *Trisvan v. The State of New York*, 2015-0490-034 (N.Y. Ct. Cl. June 5, 2015) (denying request for injunction as untimely by over two years); *Trisvan v. Annucci*, No. 14-cv-6016 MKB, 2015 WL 1966275, at *1 (E.D.N.Y. Apr. 29, 2015) (rejecting Trisvan's Section 1983 claim seeking $150 million in damages); *Trisvan v. Ercole*, No. 1:07-cv-04673-NG, 2015 WL 419685 (E.D.N.Y. Jan. 30, 2015) (dismissing petition for writ of habeas corpus as untimely by more than five years); *Trisvan v. Gould*, No 1:15-cv-00077, Doc. No. 4 (S.D.N.Y. Jan 16, 2015) (dismissing action because Trisvan brought the same claims in E.D.N.Y.); *Trisvan v. Woods*, No. 117681, slip op. at *1 (N.Y. Co. Ct. Oct. 18, 2004) (denying Trisvan's third successive application for a writ of habeas corpus).

[5] For a more complete recitation of the litigation background, please reference Witty and Hampton's Motion to Dismiss Plaintiff's Original Complaint. Aff. of Stephanie S. McGraw ¶10.

(citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Instead, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id*. at 678 (quoting *Twombly*, 550 U.S. at 570). A proper pleading "requires more than labels and conclusions," and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. Similarly, "naked assertions devoid of further factual enhancement" must be disregarded. *Id*. (quotation omitted).

Although *pro se* pleadings are construed liberally, and liberal construction requires a favorable view of the facts as pled, this neither permits nor requires the Court to read into "arguments that [*pro se*] submissions themselves do not 'suggest.'" *Triestsman v. Fed. Bureau of Prisons*, 470 F.3d 471, 477 (2d Cir. 2006) (citations omitted). *Pro se* status likewise "does not exempt a party from compliance with relevant rules of procedural and substantive law." *Traguth v. Zuck*, 710 F.2d 90, 95 (2d Cir. 1983).

IV. ARGUMENT

A. Personal Jurisdiction Still Does Not Exist Over Defendants Witty and Hampton And Plaintiff's Amended Complaint Against Them Should Again Be Dismissed Under Rule 12(b)(2).

The Court dismissed Plaintiff's Original Complaint against Witty and Hampton because it did not "show that [Witty and Hampton] had any contacts with New York to permit the Court to exercise personal jurisdiction over them." Order at 8. Plaintiff's Amended Complaint fares no better. Both Witty and Hampton are still residents of the United Kingdom with no substantial contacts with the State of New York. They still did not manufacture or distribute any medications, including Wellbutrin®, in their individual capacities, or have any involvement in Plaintiff's alleged use of the drug. The company that they helped run,[6] the United Kingdom-

[6] Sir Andrew Witty retired as CEO of GSK plc in March 2017.

based GSK plc, remains a separate and distinct legal entity from GSK LLC, the manufacturer and distributor of Wellbutrin®.

Plaintiff tacitly acknowledges each of these truths, but nevertheless maintains that the Court has specific jurisdiction over Witty and Hampton on the basis of the "effects doctrine." Accepted by the Supreme Court in *Calder v. Jones*, the "effects doctrine" or "effects test" asks whether the nonresident defendant "purposefully directed" tortious conduct towards the forum state. 465 U.S. 783, 778–90 (1984). In order to satisfy the *Calder* effects test, a foreign defendant must have expressly directed its actions towards the forum state with the knowledge that the conduct would harm in-state plaintiffs. *See Simon v. Philip Morris, Inc.*, 86 F. Supp. 2d 95, 128 (E.D.N.Y. 2000). "Mere untargeted negligence" will not suffice. *Id.* (quoting *Calder*, 465 U.S. at 789).

While it is difficult to discern what conduct Plaintiff specifically attributes to Witty and Hampton (or to any of the defendants in this litigation) on account of his lax use of the term "Defendants," nowhere in the Amended Complaint has Plaintiff pleaded facts alleging that Witty and Hampton individually had any direct involvement in the actions giving rise to this litigation.[7] The closest he comes is his new and spurious allegation that Witty and Hampton "maintain joint control and hold a majority of … shares" in GSK LLC. Am. Compl. at 5. This statement is false. Witty and Hampton were officers and directors of GSK plc, not GSK LLC, and there are no individual shareholders of GSK LLC, as it is ultimately a wholly owned subsidiary of GSK plc, which is not a party to this action.[8] Aff. of Stephanie S. McGraw ¶6. For these reasons, the Court

[7] Finding jurisdiction over an individual in New York requires a showing that the individual did business in New York in their personal capacity, not simply as an officer of a corporation that does business in New York. *See Ontel Prods., Inc. v. Project Strategies Corp.*, 899 F. Supp. 1144, 1148 n.5 (S.D.N.Y. 1995).

[8] Even if GSK plc were a party, Plaintiff could not impute GSK LLC's jurisdictional contacts in New York to GSK plc. *Chichelo v. Hoffman–La Roche Inc.*, No. 97-cv-4591, 1997 WL 654637, at *2

continues to lack personal jurisdiction over both defendants, and they should be dismissed from Plaintiff's Amended Complaint under Federal Rule of Civil Procedure 12(b)(2).[9]

B. Plaintiff's Amended Complaint Against Sir Witty, Sir Hampton and GSK LLC Should Be Dismissed Under Rule 12(b)(6).

Plaintiff's Amended Complaint against Witty, Hampton, and GSK LLC does not "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570).

1. Plaintiff's Amended Complaint Fails to Give GSK Defendants Adequate Notice.

The Second Circuit has recognized that "'[b]y lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [a] complaint fail[s] to satisfy [Rule 8's] minimum standard.'" *Stratakos v. Nassau Cty.*, No. 15-cv-7244, 2016 WL 6902143, at *7 (E.D.N.Y. Nov. 23, 2016) (quoting *Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2d Cir. 2001)). Plaintiff's Amended Complaint makes general allegations regarding the conduct of "Defendants," but fails to specify the conduct attributed to each individual defendant. Moreover, the Complaint fails to identify the causes of action for which Plaintiff seeks recovery. These deficiencies do not provide GSK Defendants sufficient notice of Plaintiff's claims necessary to prepare their defenses and, therefore, dismissal is warranted.

2. Plaintiff's Claims Related to Alleged Weight Gain, Hypertension and Gynecomastia Injuries Are Untimely.

Although the theories of liability are unclear, Plaintiff's claims are undoubtedly founded on principles of personal injury. In New York, where "the essence of [a] matter is the plaintiff's

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(S.D.N.Y. Oct. 21, 1997) ("The presence of a wholly owned subsidiary in New York is normally an insufficient basis for establishing jurisdiction.")

[9] The complaint against Witty and Hampton should also be dismissed under Rule 12(b)(5) due to insufficient service of process. Plaintiff attempted to serve Witty and Hampton – United Kingdom residents who are not employees of GSK LLC – at GSK LLC's offices in Pennsylvania. This attempt at service did not satisfy the methods of service prescribed by the Hague Convention. *See* Hague Convention, Art. 5–6, 8–10.

claim to recover damages for personal injuries ... [the] case is governed by the three-year Statute of Limitations period" applicable to personal injury claims. *Kendall v. Aegis Eng'g Servs., Inc.*, No. 1:13-cv-185, 2014 WL 3818697, at *2 (N.D.N.Y. Aug. 4, 2014) (citing *Erickson v. YMCA of Nyack*, 108 A.D.2d 720, 720 (N.Y. App. Div. 1985); N.Y. C.P.L.R. § 214-c.

Plaintiff alleges that he was first prescribed and ingested Wellbutrin® in 2001, approximately fourteen years before his original complaint was filed and well outside the three-year limitations period. Am. Compl. at 7. The Amended Complaint states that Plaintiff had reason to know "within two years of taking" Wellbutrin® and Risperdal® that the medications had caused him harm. *Id.* Specifically, Plaintiff claims that "by way of usage of these medications," he "gained close to 100lbs; had developed a case of gynecomastia, and had begun suffering from hypertension." *Id.* In New York, tort claims generally accrue upon an injury being sustained. [10] *City Store Gates Mfg. Corp. v. Empire Rolling Steel Gates Corp.*, 113 A.D.3d 718, 719 (N.Y. App. Div. 2014). Based upon these allegations, Plaintiffs' tort claims accrued in or around 2003, when Plaintiff states he suffered sudden weight gain, hypertension and gynecomastia.

3. Plaintiff's Claims Fail to Satisfy the Twombly / Iqbal Standard.

i. <u>The Amended Complaint Does Not Plead Facts Sufficient to Hold Sirs Witty and Hampton Personally Liable.</u>

It is well-established that "absent bad faith or fraud, corporate officers and directors acting within the scope of their employment cannot be held personally liable for breaches of contract or tortious acts committed by their corporations." *Rella v. N. Atl. Marine, Ltd.*, No. 02-

[10] If a plaintiff does not reasonably know the cause of his or her injury at the time the injury is sustained, New York law permits such a plaintiff to "file a claim within one year of discovering the cause, provided that discovery of the cause occurred within five years of actual or constructive discovery of the 'injury' itself." *Braune v. Abbott Labs.*, 895 F. Supp. 530, 543 (E.D.N.Y. 1995) (citing New York Civil Practice Law and Rules section 214–c(4)). This tolling provision is not applicable here because Plaintiff did not file his claim within six years of discovering his alleged injuries.

cv-8573, 2004 WL 1418021, at *9 (S.D.N.Y. June 23, 2004) (citations omitted); *Meyer v. Holley*, 537 U.S. 280, 286 (2003). Plaintiff fails to explain how any individual acts by Witty or Hampton led to the injuries Plaintiff attributes to his ingestion of Wellbutrin®. Instead, Plaintiff relies on generic allegations and legal conclusions relating to Witty and Hampton's supposed failure to warn and negligence. Plaintiff provides no factual support to demonstrate that Witty or Hampton, in their individual capacities, owed Plaintiff any duty, let alone in the context of the prescription medications Plaintiff allegedly ingested.

ii. The Amended Complaint Does Not Adequately Plead Causation.

Because Plaintiff's Amended Complaint does not delineate any particular causes of action, GSK Defendants are left to guess at what arguments Plaintiff is attempting to raise. *See Ohuche v. Merck & Co.*, 903 F. Supp. 2d 143, 150 (S.D.N.Y. 2012). A broad reading suggests that Plaintiff endeavors to assert claims for failure to warn, [11] defective design[12] and fraud.[13] No matter the product liability claim, a requisite element of each is proof that that Wellbutrin® was the proximate cause of an actionable harm. *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 252 (E.D.N.Y. 1999) (holding that "causation is an element not only in … strict products liability claims, but in … negligence, breach of warranty, fraud, misrepresentation and per se negligence claims as well"). Plaintiff has failed to adequately plead that Wellbutrin® was the proximate cause of his injuries.

[11] *See* Am. Compl. at 6 ("Defendants have a duty to provide consumers with warnings of hidden product dangers."), *See also id.* ("Defendants had a duty to warn Plaintiff about such potential life threatening conditions that could result from usage of their medication. Their failure to uphold such duty to warn and their deliberate withhold of the truth resulted in failure to protect plaintiff's individual rights….").

[12] *See* Am. Compl. at 9 ("Despite reports of both medications causing liver damage and injury, the distribution of these drugs were not discontinued."). *See also id.* at 11 ("In spite of what studies shown and demonstrated to these manufacturers, they never altered the makeup of such composition of these drugs.").

[13] *See* Am. Compl. at 9 ("Defendants constructed a marketing scheme spearheaded by Alex Gorsky and others to lure the public into signing on to these drugs."). *See also id.* ("Defendants actions were deliberate, sadistic, and malicious.").

"To establish proximate cause in a products liability case, a plaintiff must show that the defect in the product was a substantial factor in causing the injury." *Nutting v. Ford Motor Co.*, 180 A.D.2d 122, 131 (N.Y. App. Div. 1992). The Amended Complaint lumps together Wellbutrin® and Risperdal® and summarily concludes that "these medications" caused Plaintiff's injuries. Plaintiff does not, however, assert that Wellbutrin® was individually a substantial factor in causing Plaintiff's injuries. *See Weddle v. Smith & Nephew, Inc.*, No. 14 C 09549, 2016 WL 1407634, at *3 (N.D. Ill. Apr. 11, 2016) (noting that Supreme Court made clear in *Iqbal* that "the allegations against any particular defendant must plausibly allege liability based on that defendant's own conduct"); *Bockrath v. Aldrich Chem. Co., Inc.*, 980 P.2d 398, 405, (Cal. 1999) ("The law cannot tolerate lawsuits by prospecting plaintiffs who sue multiple defendants on speculation that their products may have caused harm over time through exposure to toxins in them, and who thereafter try to learn through discovery whether their speculation was well-founded.").

Plaintiff provides no support whatsoever for his conclusion that Wellbutrin® caused him harm. Instead, Plaintiff declares that an unnamed "medical professional" at some unknown point in time and at some unnamed location told Plaintiff that "the medication he was being prescribed … had been said to have caused liver injury and damage." Notably, Plaintiff does not specifically state that "the medication" included Wellbutrin® or that the medical professional told him Wellbutrin® may have caused *his* injuries.

"Although Rule 8 does not require plaintiffs to plead a theory of causation, it does not protect a legally insufficient claim." *In re Methyl Tertiary Butyl Ether (MTBE) Prod. Liab. Litig.*, 379 F. Supp. 2d 348, 370 (S.D.N.Y. 2005). This Court in *Reed v. Pfizer, Inc.* rejected the notion that a complaint can pass pleading muster by "alleging factual content sufficient only to make

plausible that [the plaintiff] ingested [a drug] and thereafter suffered serious harm." 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012). "To allow such a naked claim to go forward would merely green light for plaintiffs an expedition designed to fish for an '*in terrorem* increment of the settlement value, rather than a reasonably founded hope that the discovery process will reveal relevant evidence.'" *Id.* (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)). Without more than a barebones assertion that he ingested Wellbutrin® and later suffered harm, Plaintiff's Amended Complaint fails to set forth a plausible basis for causation, which is necessary to state a products liability claim. Therefore, Plaintiff has failed to allege facts sufficient to state any cognizable legal claim against GSK Defendants.

iii. Plaintiff's Failure to Warn Claim is Not Plausible.

In order to establish a prima facie case against a prescription drug manufacturer for failure to warn under New York law, "a plaintiff must demonstrate that the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." *Glucksman v. Halsey Drug Co., Inc.*, 160 A.D.2d 305 (N.Y. App. Div. 1990). The elements "remain the same under New York law regardless of whether they sound in negligence or strict liability." *Bee v. Novartis Pharms. Corp.*, 18 F. Supp.3d 268, 282–83 (E.D.N.Y. 2014). Plaintiff cannot assert a failure to warn claim against GSK Defendants because the claim is barred by the learned intermediary doctrine, and because Plaintiff does not set forth sufficient facts to show how the Wellbutrin® warning label was inadequate.

Under the learned intermediary doctrine, a pharmaceutical manufacturer's duty to warn of a drug's potential risks runs to the prescriber, not the consumer. *Martin v. Hacker*, 628 N.E.2d 1308, 1311 (N.Y. 1993) ("The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side

effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.") (citations omitted). Plaintiff's Amended Complaint states that Plaintiff believes he was not properly warned of the risks associated with Wellbutrin®, but it critically fails to allege that GSK LLC provided inadequate Wellbutrin® warnings to Plaintiff's *treating healthcare providers*. The Amended Complaint also does not assert that, had GSK LLC provided proper warnings to Plaintiff's providers, then those providers would not have prescribed Plaintiff Wellbutrin®. *See Cubbage v. Novartis Pharm. Corp.*, No. 5:16-cv-129, 2016 WL 3595747, at *5–6 (M.D. Fla. July 5, 2016) (dismissing the plaintiff's claims because he did not "allege in his complaint that his physicians would have made a different prescribing decision had they been provided with an adequate warning").

All that can be reasonably gleaned from the Amended Complaint is that GSK LLC's supposed failure to warn "resulted in failure to protect plaintiff's individual rights and Plaintiff's right of self determination as well as Plaintiff's rights to determine his own fate." Am. Compl. at 11. While one cannot quarrel with Plaintiff's desire to determine his own fate, the learned intermediary doctrine provides that it is Plaintiff's doctors who are in the best position to "evaluat[e] the patient's needs, assess[] the risks and benefits of available drugs, and prescribe[e] and supervis[e] their use." *Glucksman*, 160 A.D.2d at 307 (citing *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 61 (N.Y. App. Div. 1979)). Even so, Plaintiff never actually states that had he received additional Wellbutrin® warnings he would not have ingested Wellbutrin®. Because the Amended Complaint does not assert that GSK LLC failed to warn Plaintiff's doctors or that such a failure to warn was the proximate cause of his injuries, Plaintiff cannot maintain a failure to warn claim.

Plaintiff also cannot successfully bring a failure to warn claim because his Amended Complaint is altogether silent on the content of the Wellbutrin® product labeling that he claims was inadequate. This Court and others within the Second Circuit "consistently have held that mere assertions that warnings on product labels are inadequate constitute conclusory statements lacking in empirical support." *Morrison v. Hoffmann-La Roche, Inc.*, No. 14-cv-4476, 2016 WL 5678546, at *8 (E.D.N.Y. Sept. 29, 2016); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012) ("[A] failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicating how the provided warnings were inadequate.").

Contrary to Plaintiff's assertion that the Wellbutrin® label was inadequate, since at least 2001, the label has specifically addressed all of the injuries alleged in Plaintiff's Amended Complaint – hypertension, gynecomastia, hepatic (liver) impairment, and weight gain – a matter of which judicial notice may be taken. Aff. of Stephanie S. McGraw ¶20; *Becker v. Cephalon, Inc.*, No. 14-cv-3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (recognizing court's ability to take judicial notice of the contents of drug labels). The 2001 Wellbutrin® labeling provided this hypertension warning:

> In clinical practice, hypertension, in some cases severe, requiring acute treatment, has been reported in patients receiving bupropion alone and in combination with nicotine replacement therapy. These events have been observed in both patients with and without evidence of preexisting hypertension.

Aff. of Stephanie S. McGraw ¶20. The Adverse Reactions section of the same labeling cautions that GSK LLC received clinical trial or postmarketing reports of gynecomastia and liver damage. *Id.* The labeling also includes a notice that bupropion passes through the liver and thus, patients with signs of liver impairment should be closely monitored for possible toxic accumulations of the drug in the hepatic system. *Id.* Additionally, the labeling explains that studies in dogs

receiving large long-term doses of bupropion reported "various histologic changes … in the liver" and "laboratory tests suggesting mild hepatocellular injury were noted." *Id.*

For all of these reasons, Plaintiff's Amended Complaint does not plausibly plead a failure to warn claim.

iv. Plaintiff's Defective Design Claim is Not Plausible.

In order to plead defective design claim under New York law, a plaintiff must show that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing plaintiff's injury." *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 254 (E.D.N.Y. 2014). Plaintiff's Amended Complaint cannot plausibly be read as pleading a sufficient design defect cause of action for the simple reason that it lacks an allegation that GSK LLC could feasibly have designed Wellbutrin® in a safer manner. *See Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (dismissing design defect claim because plaintiff failed to plead a feasible alternative design).

Plaintiff suggests that the appropriate course of action to resolve what he believed to be a defectively designed drug would have been for GSK LLC to take Wellbutrin® off the market altogether. *See* Am. Compl. at 9 ("Despite reports of [Wellbutrin® and Risperdal®] causing liver damage and injury, the distribution of these drugs were not discontinued."). However, the Second Circuit holds that "a design-defect claim will not stand if the only alternative is an outright ban." *S.F. v. Archer Daniels Midland Co.*, 594 F. App'x 11, 12–13 (2d Cir. 2014). By

failing to offer that there was a feasible safer design alternative for Wellbutrin®, Plaintiff cannot assert a defective design claim.[14]

v. Plaintiff's Fraud Claim is Not Plausible.

"[I]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "A plaintiff bringing a fraud claim must allege 'the time, place, speaker, and sometimes even the content of the alleged misrepresentation.'" *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246, 259 (E.D.N.Y. 2014) (quoting *Ouaknine v. MacFarlane*, 897 F.2d 75, 79 (2d Cir. 1990)). *See also Premium Mortgage Corp. v. Equifax, Inc.*, 583 F.3d 103, 108 (2d Cir. 2009) (providing elements of fraud under New York law). Plaintiff references a number of supposed acts of "fraud" and "malfeasance," but lacking in the Amended Complaint is any factual support for these wild accusations of wrongdoing. Plaintiff does not identify any single alleged representation made by GSK Defendants or explain who made the representation or why the representation was false. Also clearly missing from the Amended Complaint are any fraudulent statements that GSK LLC specifically made *to Plaintiff or his doctors* that were relied upon to his detriment.

As discussed briefly above, Plaintiff also improperly pleads any potential fraud claims by employing a style of "group pleading" that the Second Circuit rejects. "Group pleading," wherein a Plaintiff brings "lumped-together accusations of wrongdoing by undifferentiated groups of defendants," fails to satisfy the Rule 9(b) particularity requirement. *Sedona Corp. v. Ladenburg Thalmann & Co., Inc.*, No. 03-cv-3120, 2005 WL 1902780, at *12 (S.D.N.Y. Aug. 9, 2005); *Apace Commc'ns, Ltd. v. Burke*, 522 F. Supp. 2d 509, 517 (W.D.N.Y. 2007). Plaintiff

[14] A design defect claim is also not feasible because the Amended Complaint does not establish how Wellbutrin® as designed posed a substantial likelihood of harm. Plaintiff makes only conclusory allegations like, "studies shown and demonstrated to" GSK LLC "the dangers of" Wellbutrin®." Am. Compl. at 11. "Conclusory statements that the product has a design defect do not suffice." *Savage v. Beiersdorf Inc.*, No. 13-cv-0696, 2013 WL 5532756, at *6 (E.D.N.Y. Sept. 30, 2013).

makes no effort to specifically allege the fraud perpetrated by GSK LLC versus that of Janssen Pharmaceuticals, or the various individual executive defendants. He instead fuses the parties into "Defendants," seemingly claiming that they acted in unison to defraud consumers of both Wellbutrin® and Risperdal®.[15] The Amended Complaint provides a flagrant example of group pleading that falls short of Rule 8's minimum pleading standards much less the heightened Rule 9(b) standards. Accordingly, Plaintiff's attempt to rely on a fraud theory is implausible.

V. CONCLUSION

For the foregoing reasons, Defendants Witty, Hampton, and GSK LLC respectfully request that the Court grant their Motion to Dismiss Plaintiff's Amended Complaint under Rule 12(b)(2), (5) and (6) and dismiss with prejudice Plaintiff's claims against them.

Dated: May 26, 2017

Respectfully submitted,

/s/ Stephanie S. McGraw
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[15] For instance, without any accompanying explanation, Plaintiff declares that "Defendants conspired with one another to introduce dangerous drugs to the public sector…." Am. Compl. at 9–11.

CERTIFICATE OF SERVICE

I hereby certify that, on May 26, 2017, a true and correct copy of the foregoing was served upon the following via certified U.S. Mail:

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/s/ Stephanie S. McGraw
Stephanie S. McGraw